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ABBOTT CARDIOVASCULAR SYSTEMS INC./  
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EXAMINER
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FOREMAN, JONATHAN M

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/746,144  
Filing Date: December 21, 2000  
Appellant(s): CORNISH ET AL.

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Louis M. Troilo  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3/16/09 appealing from the Office action mailed 5/30/08.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is essentially correct. However, Appellant states that "The second set of properties have been altered from the first set of properties **by atmospherically isolating a section of the superelastic member and alloying the second section by exposing the section to a diffusible element**". The Examiner would like to point out that claim 7 only recites "treating" the second section and does not require atmospherically isolating a section.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

JP 04187159A	Yamauchi et al.	7-1992
5,722,981	Stevens	3-1998
6,325,766	Anderson et al.	12-2001
6,428,317	Abel	8-2002
6,969,397	Ginn	11-2005

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 and 20 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,325,766 to Anderson et al. in view of US Patent No. 5,722,981 to Stevens.

In regard to claims 7 and 20 - 26, Anderson et al. disclose an elongated medical device having a superelastic member (10) having a first section (12) with a first set of properties and an adjacent second section (14) having a second set of properties (Col. 2, lines 38 – 62). The second section includes a distal end that is at least about 3 cm in length (Col. 3, lines 1 – 10). Anderson et al. discloses using any pseudo- or super-elastic alloys or shape memory nickel-titanium alloys (Col. 2, lines 38 – 43) for the second section, but fails to disclose the alloy including an easily diffusible

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element consisting of oxygen or hydrogen. However, Stevens teaches a nickel-titanium alloy having a reduced superelasticity which includes oxygen or hydrogen (Col. 3, lines 41 – 47). The claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Anderson et al. and Stevens teach the use of known superelastic nickel-titanium alloys, it would have been obvious to one skilled in the art at the time of the invention to substitute one alloy for the other to achieve the predictable results of allowing the medical device to have a pre-formed shape, be stressed into another shape, and then return to its pre-formed shape.

Claims 7 and 21 - 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. ('159) in view of U.S. Patent No. 6,428,317 to Abel.

In regard to claims 7 and 21 - 25 Yamauchi et al. ('159) discloses a superelastic member having a first section (2a) with a first set of properties and an adjacent second section (2) having a second set of properties which have been altered from the first set of properties by treating the second section with an easily diffusible element (Page 9, lines 7 – 8), wherein the superelastic member comprises a nickel-titanium alloy (Page 5, lines 11 – 17). The second section of the superelastic member having the altered properties includes a distal end (Page 5, line 18 - Page 6, line 2). The distal end is at least about 3 cm in length (Page 11, line 16). However, Yamauchi et al. fail to disclose the easily diffusible element being selected from the group consisting of oxygen, hydrogen and nitrogen. However, Abel teaches that heat treatments and /or the addition of trace elements such as oxygen (O) and nitrogen (N) to nickel-titanium alloys can have very significant effects on desired superelastic properties and performance of the material (Col. 3, line 65 – Col. 4, line 14). The claims would have been obvious because the technique for improving a particular class of devices was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the

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teaching of the technique for improvements in other situations. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the member as disclosed by Yamauchi et al. to include an easily diffusible element from the group consisting of oxygen, hydrogen and nitrogen as taught by Abel in order to allow a portion the core to exhibit enhanced superelastic properties.

#### **(10) Response to Argument**

Appellant's arguments have been fully considered but they are not persuasive. The claimed invention is a product by process type claim. As such, the claimed invention is not limited to the manipulations of the recited steps, only the structure implied by the steps. MPEP 2113. In the present case, the invention includes a superelastic member having a first section and a second section including oxygen, hydrogen or nitrogen. Appellant asserts that Anderson et al. fail to disclose a superelastic member having more than one section and each section having a different set of properties. However, the Examiner disagrees. Anderson et al. states that the proximal portion may be formed from conventional materials. Conventional materials for guidewires are known to include superelastic alloys (See U.S. Patent No. 6,969,397 to Ginn; Col. 14, lines 23 – 27). As such, Anderson et al. disclose an elongated device having a superelastic member having a first section (12) and a second section (14). Anderson et al. disclose using any pseudo- or super-elastic alloys or shape memory nickel-titanium alloys (Col. 2, lines 38 – 43) for the second section. Because Anderson et al. discloses using any pseudo- or super-elastic alloys, a reasonable expectation of success exists with the proposed modification using the superelastic alloy containing oxygen or hydrogen disclosed by Stevens. Because Stevens discloses diffusible element as claimed in conjunction with a superelastic alloy, it is inherent that the diffusible element at least partially results in reduced superelasticity. Appellant asserts that there is no disclosure in Stevens as to how the diffusible elements are

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introduced. However, the diffusible elements are considered by the Examiner to be introduced into the alloy by "treating" the alloy. Claim 7 merely states that the section has been altered by "treating" and provides no specificity as to how the diffusible element is introduced. Furthermore, as stated above, such a limitation is product by process limitation and the claim is not limited to the manipulations of the recited steps, only the structure implied by the steps. In this case, the end result is a superelastic alloy having a diffusible element; this feature is taught by Stevens. In regard to the rejection over Yamauchi et al. ('159) in view of U.S. Patent No. 6,428,317 to Abel, Appellant asserts that Yamauchi fails to disclose treating the guidewire with an easily diffusible element. However, Yamauchi discloses the superelastic member including carbon (Constitution, lines 1 – 3). It is noted that page 4, lines 12 - 15 regard carbon as an easily diffusible element. It is also noted that Appellant cancelled this feature from the claims once Yamauchi was applied as a reference. Appellant asserts that there is no disclosure in Abel as to how the diffusible elements are introduced. However, the diffusible elements are considered by the Examiner to be introduced into the alloy by "treating" the alloy. Claim 7 merely states that the section has been altered by "treating" and provides no specificity as to how the diffusible element is introduced. Furthermore, as stated above, such a limitation is product by process limitation and the claim is not limited to the manipulations of the recited steps, only the structure implied by the steps. In this case, the end result is a superelastic alloy having a diffusible element; this feature is taught by Stevens. Abel teaches the structure (i.e. a superelastic member having oxygen, hydrogen or nitrogen) of the claimed invention. The Examiner maintains that one of ordinary skill in the art at the time of the invention to modify the member as disclosed by Yamauchi et al. to include an easily diffusible element from the group consisting of oxygen, hydrogen and nitrogen as taught by Abel in order to allow a portion the core to exhibit enhanced elastic properties.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Jonathan ML Foreman/

Examiner, Art Unit 3736

Conferees:

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

/Nathan Newhouse/

Supervisory Patent Examiner, Art Unit 3782

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.